Patentability of Claims 11-16 Based on Unexpected Results– Applicant respectfully argues that it would not have been obvious to one of ordinary skill in the art to choose the range between 0.25% and 1.5% flavoring in the gelatin capsules for *improving* the palatability of a dose encapsulated therein. In *In re Boesch*, 205 USPQ 215 (CCPA 1980) the court set criteria for rebutting obviousness of a range. In *Boesch* a metal alloy composition was optimized by setting four parameters according to a particular criteria set forth. The alloy compositions were all within the well-defined ranges of the prior art, and were nearly identical with prior art compositions. The *Boesch* court set the criterion for rebutting a prima facie case of obviousness of a range "where results of optimizing a variable, which was known to be result effective, are unexpectedly good; proof of unexpected results properties may be in the form of direct or indirect comparison testing the claimed compounds and closest prior art." In *Boesch* the court held that the applicant did not meet the burden, because he did not sufficiently meet the burden of comparing his range to the many close prior art compositions.

In the instant case, the '961 patent *does not disclose a range of concentrations for the flavoring in gelatin capsule shells*, but merely states that flavoring is as an "optional ingredient". No concentrations were given, and no indication that concentration of flavoring was an important variable or would be expected to improve the palatability of an encapsulated dose.

Referring to the Exhibits data are presented to establish the following unexpected results:

1. At least ten different natural flavorings were tested including strawberry, lemon, peppermint, peach, orange and butterscotch with gelatin capsules. In each flavor tested, the flavoring improved the taste only in an unexpectedly narrow range concentrations, in the range between 0.25% to 1.75% weight per cent in each case. This result was unexpected to the applicant and to the lab that made the samples for him.
2. The testing was conducted in two steps, first to find a palatable range and then to find a further preferred range. *Tests of flavor addition to the gelatin capsules and fish oil were conducted independently (see next paragraph).*
3. The testing was started with concentrations of 8-10% for each flavor and went down to 0.25-0.5%. In all cases the palatability was better at the lower concentrations and in no case was a capsule consumable with a flavor content of the shell greater than 3%.
4. The flavor of the capsules was evaluated by panels, each comprising at least eight adults and from three to five children. The children's inputs were given considerable weight.

It will be noted that while the Applicant's business interest for the testing presented in the Exhibits was fish oil capsules, *the data reported included independent testing of flavoring the capsules and flavoring the oil* (see item no. 6 on Exhibit 2, as well as the laboratory report attached to Exhibit 1 where extensive results are reported separately for the shells and oil flavored by strawberry flavorings). *The claimed range of 0.25% to 1.50% in the application applies to the palatable range for gelatin shells alone.* Interactions of the shell with the oil depending on composition of the oil and the nature of the flavor were observed, however these variations affected the preferred position *within* the range.

Applicant argues that the one of ordinary skill in the art could not have anticipated that there would be a narrow palatable range of concentrations based on the disclosure in U.S. '961, and that he has compared his range within a wide range of possible values as required to meet his burden under *Boesch*,. It is respectfully requested that Claims 11-16 be allowed.

Patentability of Claims 7-10

Applicant respectfully argues that the teaching in U.S. '961 is not sufficient to enable one of ordinary skill in the art to make a flavored fish oil capsule as claimed in claims 7-10. The entire teaching about flavored capsules in '961 is as follows: " Other optional components which can be incorporated into the soft gelatin shells include colorings, flavorings, preservatives, anti-oxidants, essences, and other aesthetically pleasing components."

The invention of U.S. '961 is substantially different from the embodiment as claimed in claims 7 – 10. In U.S. '961, the compositions are a soft gelatin capsule encapsulating a pharmaceutical composition which comprises at least one difficultly soluble pharmaceutical dissolved in polyethylene glycol and polyvinylpyrrolodone (Summary). The soft gelatin shells in U.S. '961 is compounded to rapidly dissolve or rupture in the gastrointestinal tract thereby introducing the pharmaceutical actives into the physiological system (col. 10, line 17-21). This is accomplished by a gelatin shell, as originally prepared [as originally prepared is defined as the five minutes *after* the evaporation step is complete (col. 3, line 65-69)] comprising 15 to 50% water, most preferably 30 to 40% water (col. 9, line 32-35). Thus a capsule as disclosed in '961 is a rapidly dissolving gelatin shell having 15% to 50% water composition, optional flavoring, encapsulating a dose such as a nutritional supplement including fatty acid dissolved in polyethylene glycol and polyvinylpyrrolodone (1/2 or more of the dose).

In contrast, claim 7 is a gelatin capsule having about 6% to 10% water, encapsulating a dose which consists essentially of fish oil. Applicant's declarations show that the range in water concentration is necessary for a stable fish oil capsule, and that flavoring makes the gelatin shells more sensitive to water content.

It can be seen that the teachings in U.S. '961 needs to be modified significantly to get to claim 7, at least with respect to the difference in water content and whether the dose is dissolved in polyethylene glycol and polyvinylpyrrolodone or consists essentially of fish oil. Although, U.S. '961 could be so modified, there is no suggestion or motivation in the reference to do so, and to do so would render '961 entirely unsuitable for its intended purpose since nothing would be left of the '961 invention except the optional flavoring. It is therefore respectfully argued that U.S. '961 does not render it obvious to add flavoring to the gelatin capsules in Claim 7, based on the many precedents relating to the need for motivation to modify a reference.

At best, '961 is the type of reference that "gives general guidance and is not at all specific as to the particular form of the claimed invention or how to achieve it" which the Board has characterized as an "invitation to explore" which may make an approach "obvious to try" but not make the invention obvious. *Ex parte Obukowicz*, 27 USPQ 2d 1063 (B.P.A.I. 1992).

Allowance of claims 7-10 as amended is therefore respectfully requested.

CONCLUSION

It is respectfully submitted that the applicant has overcome the rejections to remaining claims 7 through 16, by amendment, argument, and evidence of superior and unexpected results, and reconsideration and allowance of all outstanding claims is now hereby respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully Submitted,

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